



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,256	10/09/2001	Gyorgy Lajos Kis	OP/4-30969A/N1/CVH21	6198
1095	7590	05/13/2005	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			NICOLAS, FREDERICK C	
			ART UNIT	PAPER NUMBER
			3754	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s) ^{SA}	
	09/973,256	KIS ET AL.	
	Examiner	Art Unit	
	Frederick C. Nicolas	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/2005 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 34-35,41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller 4,088,166 in view of Czaplinski et al. 3,709,365.

Miller discloses a pharmaceutical package (col. 1, ll. 8-15), which comprises a closed polypropylene bottle/barrel (10) in which is disposed a solution as seen in Figure 1, wherein the solution does not fill the bottle completely and some air is disposed in the bottle (col. 6, ll. 11-22), a cap (32), a neck (14), the bottle has a bottom portion that has a concave configuration (22). Miller lacks after autoclaving the package at at least 121°C and for at least 20 minutes, suffers no deformation, does not shrink, and does not explode and where the package retains a sufficiently high squeezability to dispense

Art Unit: 3754

the solution. Czaplinski et al. teach the use of autoclaving a polypropylene material at about 115°-125°C. from 20-30 minutes (col. 2, ll. 49-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Czaplinski et al. onto Miller's package by autoclaving the package at at least 121°C and for at least 20 minutes, as taught by Czaplinski et al. in (col. 2, ll. 49-58), in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes.

4. As to claim 41, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Miller and Czaplinski et al. as such, in order to comply with the requirements of the European Pharmacopoeia, 3rd edition (1997), as such is notoriously well known in the art.

5. Claims 36-40,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller 4,088,166 in view of Czaplinski et al. 3,709,365 as applied to claim 35 above, and further in view of Carter (EP 0322134).

Miller-Czaplinski et al. in combination have taught all the features of the claimed invention except that the cap being threaded onto the neck. Carter teaches the use of a container (20) threaded neck (26b) and a threaded cap (22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Carter's teaching onto the neck of Miller and Czaplinski et

Art Unit: 3754

al., in order to provide an alternate means of attaching the cap onto the container neck for tight sealing.

As to claim 37, the claimed subject matter "the bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260.

At the time the invention was made, It would have been an obvious matter of design choice to a person of ordinary skill in the art to have made the bottle and the nozzle tip of Miller and Czapinski et al of Appryl 3020 SM 3, and the cap of HDPE GC 7260, because applicant has not disclosed that the bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the bottle, the nozzle tip and the cap of Miller and Czapinski et al, because the bottle, the cap and the nozzle tip of Miller and Czapinski et al. form an enclosed container.

Therefore, it would have been an obvious matter of design choice to modify the bottle, the cap and the nozzle tip of Miller and Czapinski et al. to obtain the invention specified in claim (37).

As to claim 39, the claimed subject matter, the bottle has a wall-thickness in the range of 0.3 mm to 0.6 mm, as well as the claimed subject matter in claim 40.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wall-thickness of Miller and Czapinski et al as such, since it has been held that where the general conditions of a claim are disclosed in the

Art Unit: 3754

prior art, discovering the optimum or workable ranges involves only routine skill in the art. As per MPEP 2144.05

As to claim 42, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Miller and Czapinski et al. as such, in order to comply with the requirements of the European Pharmacopoeia, 3rd edition (1997), as such is notoriously well known in the art.

Response to Arguments

6. Applicant's arguments filed 5/21/2004 have been fully considered but are moot in view of the new ground of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kido et al. 6,129,925 and Novitch 3,826,059 disclose other types of pharmaceutical package.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (571)-272-4931. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

Art Unit: 3754

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Y Mar, can be reached on 571-272-4906. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FN
May 9, 2005

 5/9/05
Frederick C. Nicolas
Patent Examiner
Art Unit 3754